K090173

FEB - 5 2009

Attachment 1
Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

General Information:

Trade Name:	NeuViz 16 Multi-slice CT Scanner System
Common Name:	CT Scanner
Classification Name:	21 CFR Part 892.1750 Computed Tomography X-ray System
Classification:	Class II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard, 21 CFR 1020.30 and 1020.33 IEC 60601-1: 1995, Medical electrical equipment--- Part 1: General requirements for safety IEC 60601-1-1: 2000, Medical electrical equipment--Part 1: General requirements for safety-1. Collateral Standard: Safety requirements for medical electrical systems IEC 60601-1-2: 2004, Medical electrical equipment--Part 1: General requirements for safety-2. Collateral Standard: Electromagnetic compatibility—Requirements and tests IEC 60601-1-3: 1994, Medical electrical equipment--Part 1: General requirements for safety-3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment IEC 60601-1-4: 2000, Medical electrical equipment--Part 1: General requirements for safety-4. Collateral Standard: Programmable electrical medical systems IEC 60601-2-28: 1993, Medical electrical equipment--Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis IEC 60601-2-32: 1994, Medical electrical equipment-- Part 2: Particular requirements for the safety of associated equipment of X-ray equipment IEC 60601-2-44: 2002, Medical electrical equipment--- Part 2: Particular requirements for the safety of X-ray equipment for computed tomography IEC 60601-1-6: 2004, Medical electrical equipment--Part 1-6: General requirements for safety - Collateral Standard: UsabilitY

Manufacture: PHILIPS AND NEUSOFT MEDICAL SYSTEMS CO., LTD.
Neusoft Park, Hun Nan Industrial Area, Shenyang 110179, P.R.China

Distributor: NEUSOFT MEDICAL SYSTEMS CO., LTD.
No.3-11,Wenhua Road, Heping District,
Shenyang, P.R.China
Post Code : 110004

Submitter: Contact : Tianyanfang
Title : Manager of Q&R Department
Tel : 86-24-83660649
Fax : 86-24-83780480
E-Mail : Tianyanfang@neusoft.com

Summary prepared :Dec.26, 2008

Safety and Effectiveness information

Intended Uses:

The NeuViz 16 Multi-Slice CT Scanner System can be used as a whole body computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array with multislice capability up to 16 slices simultaneously. The acquired X-RAY transmission data is reconstructed by computer into cross-sectional imagers of the body from the same axial plane taken at different angles. The system is suitable for all patients.

Device Description:

The NeuViz 16 Multi-slice CT Scanner System is composed of a gantry, a patient couch, an operator console and includes image acquisition hardware and software, and associated accessories. It is designed to be a whole body X-ray computed tomography scanner which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system software is an interactive program used for X-ray scan control, image reconstruction, and image archive/evaluation.

The NeuViz 16 Multi-slice CT Scanner System uses the same materials, construction and operating principle as Phillips existing marketed product, Brilliance CT16 Scanner System.

Predicated Device:

Phillips brilliance CT16 Scanner System (K012009)

Statement of Substantial Equivalence:

The NeuViz 16 Multi-slice CT Scanner System is of comparable type and substantially equivalent to the Phillips brilliance CT16 Scanner System (K012009) that complies with the same or equivalent standards and has the same intended uses. Both of these systems use on-board high frequency High-Voltage generator to generate X-radiation from X-ray tube. The X-ray transmission data is detected by the solid-state detector and is reconstructed by the computer which has an interactive user interface. Both of these devices produce two dimensional image and 3D image that can be filmed or electronically stored for future review.

The safety and effectiveness of the "NeuViz 16 Multi-slice" is assured by adherence to Good Manufacturing Practices(GMP) 21 CFG 820 and to International Standards ISO 13485:2003.Potential hazards are indentified in a hazard analysis and controlled in the following manner:

Software safety is assured by the company procedures that conform to accepted practices. Quality assurance procedures are adhered to, and meeting the specifications and functional requirements is demonstrated via testing.

Electrical and Mechanical safety is assured by adherence to IEC 60601-1 standards.

Radiation safety is assured by compliance with 21 CFG, Subchapter J Performance standards.

Based on above considerations, it is Neusoft's opinion that the "NeuViz 16 Multi-slice" CT scanner is substantially equivalent in safety and effectiveness to predicate device: Brilliance CT 16-slice with 510(k) K012009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2009

Neusoft Medical Systems Co., Ltd
% Mr. Tamas Borsai
Responsible Third Party Official
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K090173
Trade/Device Name: NeuViz 16 Multi-slice CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 21, 2009
Received: January 23, 2009

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2
Indications for Use Statement

510(k) Number: K090173

Device Name: NeuViz 16 Multi-slice CT Scanner System

Environment of Use / Patient Population:

The NeuViz 16 Multi-Slice CT Scanner System can be used as a whole body computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array with multislice capability up to 16 slices simultaneously. The acquired X-RAY transmission data is reconstructed by computer into cross-sectional imagers of the body from the same axial plane taken at different angles. The system is suitable for all patients.

Prescription Use: YES
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use: NO
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF DEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090173